

**REMARKS**

Claims 1-3, 6, 10, 43, 46-48, 54, and 58-61 have been amended to improve antecedent basis.

The Office Action mailed October 20, 2005, has been received and reviewed. Claims 1-11 and 42-62 are currently pending in the application. Claims 1-11 and 42-62 stand rejected. Applicants have amended claims 1-3, 6, 10, 43, 46-48, 54, and 58-61 and respectfully request reconsideration of the application as amended herein.

Applicants apologize for the omission of claim 62 and its status identifier from the listing of claims submitted in the Amendment filed July 27, 2005. Applicants have included claim 62 and its status identifier in the instant response.

**Supplemental Information Disclosure Statement**

Please note that a Supplemental Information Disclosure Statement was filed herein on February 14, 2003, and that no copy of the PTO-1449 was returned with the outstanding Office Action. It is respectfully requested that an initialed copy of the PTO-1449 evidencing consideration of the cited references be returned to the undersigned attorney.

**35 U.S.C. § 112 Claim Rejections**

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse this rejection, as hereinafter set forth.

To be enabling, "the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention." M.P.E.P. § 2164. "A patent need not teach, and preferably omits, what is well known in the art." M.P.E.P. § 2164.01. In addition, "[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." M.P.E.P. § 2164. The test for determining enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." M.P.E.P. § 2164.01. "The fact that experimentation may be complex

does not necessarily make it undue, if the art typically engages in such experimentation.” *Id.*

The Examiner asserts that the specification “does not reasonably provide enablement for G protein fusion proteins which are ‘at least 75% identical to’ specific receptor sequences” and “that undue experimentation is necessary to practice the invention as claimed.” Office Action of October 20, 2005, p. 2 and 4. Contrary to the Examiner’s assertions, Applicants respectfully submit that the specification describes the claimed invention in sufficient detail that one skilled in the art can make and use the claimed invention without undue experimentation. Specifically, the specification discloses that various domains (extracellular domains, transmembrane domains, or intracellular domains) of the G protein fusion proteins are “substantially similar” to an amino acid sequence of the calcium receptor (“CaR”), an amino acid sequence of the metabotropic glutamate receptor (“mGluR”), or an amino acid sequence of the  $\gamma$ -aminobutyric acid receptor (“GABA<sub>B</sub>R”). See, p. 2, line 24 through p. 3, line 32, p. 5, lines 15-32, and p. 6, lines 5-10 of the specification. The phrase “substantially similar” is defined to include an amino acid sequence having at least 75% sequence similarity between the CaR, mGluR, or GABA<sub>B</sub>R and the domain. See, p. 3, lines 13-16 of the specification. As such, the specification provides explicit support for a G-protein fusion protein that includes an extracellular domain, transmembrane domain, and intracellular domain, each of which is at least 75% identical to an amino acid sequence of the CaR, mGluR, or GABA<sub>B</sub>R. The specification also discloses how the degree of sequence similarity between the domain and the CaR, mGluR, or GABA<sub>B</sub>R is determined. See, p. 3, lines 16-20 of the specification. In addition, the specification discloses that “[d]omains of a G-protein fusion receptor, a chimeric receptor, and G, substantially similar to a particular sequence can be readily produced using the disclosure provided herein in conjunction with information well known in the art. Substantially similar sequences can be obtained taking into account sequence information for a particular type of receptor obtained from different sources, different types of amino acids which are to some extent interchangeable, and the ease of experimentation with which functional receptor activity can be assayed.” See, p. 15, line 31 through p. 16, line 5 of the specification. The specification further describes amino acid substitutions that are used to provide substantially similar amino acid sequences, how to identify amino acids not needed for receptor activity, and how to prepare derivatives of the amino acid sequences that are

substantially similar to the CaR, mGluR, or GABA<sub>B</sub>R. See, p. 16, line 6 through p. 17, line 33 of the specification.

Since the specification provides explicit support for domains of the G-protein fusion protein having at least 75% identity to an amino acid sequence in the CaR, mGluR, or GABA<sub>B</sub>R, describes how to determine the degree of amino acid similarity, and provides guidance on how to make conservative amino acids substitutions that have minimal effect on the activity of the receptors, how to identify amino acids not needed for receptor activity, and how to prepare derivatives of the amino acid sequences that are substantially similar to amino acid sequences in the CaR, mGluR, or GABA<sub>B</sub>R, a person skilled in the art would be able to make and use the claimed invention without undue experimentation. Furthermore, since much of this information is known in the art, as acknowledged by the specification, detailed procedures for making and using the invention need not be disclosed in the specification because, as discussed above, a patent need not teach, and preferably omits, what is well known in the art. Rather, as long as the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention, the specification is enabled.

The Examiner states that the specification provides “no guidance or working examples of proteins which are 75% identical to CaR, mGluR, or GABA<sub>B</sub>R[ and] . . . no guidance as to what critical residues are required to maintain the functional characteristics of these proteins.” Office Action of October 20, 2005, p.3. The Examiner also states that “it is not predictable to one of ordinary skill in the art how to make a functional CaR, mGluR, or GABA<sub>B</sub>R protein which is less than 100% identical to the wild-type.” *Id.* Applicants note that the existence of working examples and the level of predictability in the art are merely factors to be considered when determining undue experimentation. M.P.E.P § 2164.01(a). The fact that no working examples describing a G-protein fusion protein having domains with at least 75% identity to an amino acid sequence in the CaR, mGluR, or GABA<sub>B</sub>R are present in the specification is not sufficient to render the invention non-enabled. M.P.E.P § 2164.02.

Applicants respectfully submit that the specification provides general guidance on producing and testing derivatives of amino acid sequences that are at least 75% identical to CaR, mGluR, or GABA<sub>B</sub>R to determine whether these proteins are biologically active. In addition, the

level of skill in the biotechnological arts is high and those of ordinary skill in the art recognize that some experimentation is necessary to perform even routine functions. Based on the guidance in the specification, the high level of skill in the art, and the information known in the art, one skilled in the biotechnological arts would be able to make and use the claimed invention without undue experimentation.

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

“To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” M.P.E.P. § 2163. “The description need only describe in detail that which is new or not conventional.” *Id.* “What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.” *Id.* “If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.” *Id.*

The Examiner asserts that the specification provides no guidance as to what amino acid changes (substitutions, deletions, insertions, or additions) should be made to produce a protein that is at least 75% identical to the wild-type protein. Office Action of October 20, 2005, p. 4. The Examiner also asserts that the general knowledge and level of skill in the art would not supplement the omitted information because specific guidance is needed. *Id.* at p. 4-5. However, as described above, the specification discloses how to make conservative amino acids substitutions that have minimal effect on the activity of the receptors, how to identify amino acids not needed for receptor activity, and how to prepare derivatives of the amino acid sequences that are substantially similar to amino acid sequences in the CaR, mGluR, or GABA<sub>B</sub>R. Furthermore, as acknowledged by the Examiner, amino acid changes are known in the art. Office Action of October 20, 2005, p. 4. In addition, the level of skill in the biotechnological arts is high and those of ordinary skill in the art would expect that some

experimentation is needed to perform even routine functions. Since the specification need only describe in detail that which is new or not conventional, Applicants respectfully submit that it is improper for the Examiner to state that more specific guidance is needed. Furthermore, since the specification provides general guidance regarding these aspects of the claimed invention, a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even though every nuance of the claims is not explicitly described in the specification.

#### ENTRY OF AMENDMENTS

The amendments to claims 1-3, 6, 10, 43, 46-48, 54, and 58-61 should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add new matter to the application.

#### CONCLUSION

Claims 1-11 and 42-62 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain that might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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